

## **REMARKS**

Claims 33-36, 46, 49, 51-53, 56, 59-73 are currently pending. Claims 38 and 57 are currently cancelled and claims 1-32, 37, 39-45, 47, 48, 50, 54, 55 and 58 were previously cancelled. Claims 60-73 are currently withdrawn as directed to a non-elected invention. Applicants reserve the right to pursue these claims in an application claiming priority hereto. Claim 33 is amended to incorporate the limitations of cancelled claim 38, remove “synthetic,” and to define the annular surfaces. Claim 34 is amended to correct antecedent basis in view of amended claim 33. Support for the annular surface in claim 33 and 34 is found, for example, in Figures 2 and 4. Claim 52 is amended to correct the dependency in view of the cancelled claims. Claim 59 is currently amended to remove “synthetic”. No new matter is added.

### **Examiner Interview**

Applicants would like to thank the Examiner for the Interview of August 14, 2008. In the interview the Examiner agreed that claim 33, as amended herein, is not anticipated by Schwartz. With respect to claim 34 and 51, the Examiner agreed that it would not be obvious for Schwartz to have a lining on the inside of the stent.

### **35 U.S.C. 112, 1<sup>st</sup> Paragraph Rejection**

Claims 56 and 57 were rejected under 35 USC 112, 1<sup>st</sup> paragraph, as failing to comply with the written description requirement. Regarding claim 56, the Examiner states that “the wrinkled embodiment having the feature of ‘prevent[ing] release of the medication when the structure is in the initial state’ is unsupported by the original disclosure” (Office Action, page 2). However, it is disclosed that “the lining smoothes out as the stent expands” (col 4, lines 19-21) and “the openings expand as the prosthesis expands” (page 6, lines 21-24). Thus, it would be clear to one of ordinary skill in the art that when the lining is smooth the pores are also expanded from their “wrinkled” state and are thus opened. However, in the wrinkled initial state, the wrinkles block the openings of the pores and prevent release of medication. Thus, Applicants believe claim 56 is adequately supported by the original disclosure and respectfully request withdrawal of this rejection. Claim 57 is cancelled and this rejection is thus moot.

### **35 U.S.C. 102(e) and 103(a) Rejections**

Claims 33-36 were rejected under 35 U.S.C. 102(e) as being allegedly anticipated by U.S. Patent No. 5,957,971 to Schwartz ("Schwartz"). Claims 38, 46, 49, 51-53 and 59 were rejected as being allegedly obvious under 35 U.S.C. 103(a) over Schwartz.

#### **Claim 33**

Claim 38 has been incorporated into claim 33. Regarding previously presented claims 38 and 52, the Examiner states that "a plurality of through holes would have been obvious in order to accommodate controlled rate microcapsules (column 4, lines 48-55) in such a way that the microcapsules themselves (rather than some other barrier in the lining) 'control the rate at which the therapeutic substance is provided to the blood stream or the body lumen' (column 4, lines 48-55), and such a diameter range would have led to nothing more than predictable results in that the microcapsules would be prevented from being dislodged from the lining" (Office Action, page 4). However, microcapsules are not necessarily related to through holes (or pores), but rather are dispersed through the film. The Examiner seems to suggest that the microcapsules are held within holes in the film. However, when the microcapsules are in the film, there are no through holes. Furthermore, since the microcapsules biodegrade with the film, there are never through holes in the film.

Microcapsules are known by one of ordinary skill in the art to encase a drug and biodegrade or otherwise burst to release the drug.<sup>1</sup> The above-referenced claims recite through holes in the lining to release the medication into the body. There is no teaching or disclosure in Schwartz of any through holes in the fibrin film 32 and there is no motivation to provide such through holes. Rather, Schwartz has a film of fibrin 32 that is placed directly on the treatment area of the body, that biodegrades to release the fibrin. Because the medication is mixed into the material of the film and is not simply housed in pores within the film, there is no motivation to modify this film to have through holes for dispensing the medication. Furthermore, since there are no through holes, there is no teaching or suggestion of the size of the through holes, as recited in claim 52. In the present invention, the through holes are provided to allow substances

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<sup>1</sup> It should be noted that Schwartz does not specifically describe microcapsules. Rather, Schwartz cites a number of patents that describe microcapsules. None of these references mention pores.

to diffuse through, and must be no larger than 0.5  $\mu\text{m}$  to prevent smooth muscle cells from escaping through them from the wall to the lumen of an artery (Paragraph [0025]).

Thus, Applicants believe amended claim 33 (including the limitation of cancelled claim 38), and all claims dependent therefrom, is not obvious over the Schwartz.

#### **Claim 34**

Furthermore, with respect to claim 34, Schwartz does not teach a lining on the annular interior surface. The Examiner interprets the space between the struts of the stent as the interior, which may contact the film. However, the film of Schwartz is clearly wrapped around the outside of the stent, and there is no lining on the interior annular surface. Thus, Applicants believe amended claim 34 is not obvious over the Schwartz.

#### **Claim 56**

Furthermore, with respect to claim 56, Schwartz does not teach “a lining being adapted to prevent release of the medication when the structure is in the initial state and allow release of the medication when the structure is in the expanded state.” The fibrin film of Schwartz has no mechanism to prevent drug release during implantation. Thus, Applicants believe amended claim 56 is not obvious over the Schwartz.

### CONCLUSION

The Applicants respectfully submit that this application is now in condition for allowance. Should any questions arise, the Examiner is invited to contact the undersigned at the number given below. Applicant's representative hereby requests an interview with the Examiner and will call to ascertain a date and time convenient to the Examiner's schedule. The Commissioner is authorized to charge any additional necessary fees or to credit any overpayments to Deposit Account No. 11-0600.

Respectfully submitted,

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Dated: August 28, 2008

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